

Application Number 10/731,869  
Responsive to Office Action mailed March 8, 2007

RECEIVED  
CENTRAL FAX CENTER

JUN 08 2007

### REMARKS

This amendment is responsive to the Office Action dated March 8, 2007. Applicant has amended claims 12, 21, 53, and 56, and added claims 58-61. Claims 1-31 and 33-61 are pending.

#### Amendments to the Specification

With the present amendment, Applicant has amended paragraphs [0002], [0039], [0048], [0051], [0056], [0058], [0062], and [0075] to update the serial numbers for co-pending patent applications referenced in the originally filed disclosure.

#### Claim Rejection Under 35 U.S.C. § 101

In the Office Action, claims 12, 21 and 53 were rejected under 35 U.S.C. § 101 on the basis that the claimed invention is directed to non-statutory subject matter. In particular, the Office Action reasoned that, "the claiming of structures being in contact with or implanted within the body amounts to an inferential recitation of the body . . ."<sup>1</sup> The Office Action recommended that Applicant amend the recitation of "device is implanted" in claim 12 to read "adapted to be implanted" in order to overcome the rejection under 35 U.S.C. § 101. In addition, the Office Action recommended that Applicant amend claims 21 and 53 to recite "is adapted to be shaped for implantation," rather than the "shaped for implantation."

Applicant does not agree with the Office Action's conclusion that claims 12, 21, and 53 as originally presented inferentially recite the body. However, Applicant has amended claims 12, 21, and 53 as recommended by the Office Action in order to expedite prosecution of the application. Withdrawal of the rejection of claims 12, 21, and 53 under 35 U.S.C. § 101 is respectfully requested.

#### Claim Rejection Under 35 U.S.C. §§ 102(e) and 103(a)

In the Office Action, claims 1-4, 6-9, 11-25, 27-30, 33-49, 51-54 and 56 were rejected under 35 U.S.C. § 102(e) as being anticipated by Berrang et al. (U.S. Patent No. 6,358,281). Claim 55 was rejected under 35 U.S.C. § 102(e) as anticipated by or, in the alternative, under 35

<sup>1</sup> Office Action at page 5, item 1.

Application Number 10/731,869  
Responsive to Office Action mailed March 8, 2007

U.S.C. § 103(a) as obvious over Berrang et al. Claims 5, 10, 26, 31, 50 and 57 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Berrang et al. Applicant respectfully traverses the rejection of the claims. Berrang fails to teach or suggest each and every feature of the claimed invention, and provides no teaching that would have suggested the desirability of modification to include such features.

For example, Berrang fails to teach or suggest an implantable medical device comprising a first module that includes control electronics within a first housing, a second module that includes a second housing, and an overmold that at least partially encapsulates the first and second housings, where the first and second housings are coupled, and the coupling of the first and second housings allows the housings to have a plurality of degrees of freedom of movement relative to each other, as recited by Applicant's independent claim 1.

In support of the rejection of independent claim 1, the Office Action found that "Berrang et al. discloses a first and second modules disposed within corresponding first and second housing in addition to the pliable (or bendable) bridge, which the examiner considers to be an overmold" and referenced FIG. 1 of Berrang et al.<sup>2</sup> The Office Action characterized elements 2 and 3, which are also shown in FIGS. 2 and 3, as two modules that each have a housing encapsulated by an overmold.<sup>3</sup> Applicant respectfully disagrees with the Office Action's characterization of the elements 2 and 3 of Berrang et al. as first and second modules each comprising a housing, as required by Applicant's claim 1, and the characterization of the bridge as an overmold that at least partially encapsulates housings of the elements 2 and 3.

Berrang et al. clearly and repeatedly describes its device as having a single housing ("the housing") comprising two sections.<sup>4</sup> At no time does Berrang teach or even suggest that its device includes at least a first module comprising a first housing and a second module comprising a second housing, much less an overmold that at least partially encapsulates the first and second housings, as recited by Applicant's independent claim 1.

While the Office Action discusses the elements of Berrang et al. that it considers to be first and second modules, the Office Action fails to provide an indication of what elements of Berrang et al. constitute housings of the modules. Berrang et al. fails teach or even suggest that

<sup>2</sup> Office Action at page 6, item 1.

<sup>3</sup>Id.

<sup>4</sup> Berrang, columns 3-4, lines 25-4 and column 9, lines 51-62.

Application Number 10/731,869  
Responsive to Office Action mailed March 8, 2007

elements 2 and 3 may each include a separate housing. For example, even though at column 11, lines 60-63, Berrang et al. teaches the use of a medical grade epoxy (or any biocompatible polymer) 28 to coat and encapsulate the internal components (mounted on the ceramic substrates 24 and 25) of elements 2 and 3, the epoxy does not define a housing for each element 2 and 3. Berrang specifically teaches that the outside edges of the ceramic substrates 24 and 25, or the areas over the snap domes 20 and 23 are not coated by the epoxy.<sup>5</sup> Thus, the epoxy surfaces are not housings for elements 2 and 3, because the epoxy surfaces in no way house elements 2 and 3 as required by a housing. Rather, the epoxy surfaces are merely components of elements 2 and 3.

Furthermore, the pliable bridge of the Berrang et al. is not an overmold as asserted by the Office Action. Berrang et al. merely states that the bridge joins the two housing sections.<sup>6</sup> It is unclear how this bridge is an overmold that at least partially encapsulates first and second housings of respective modules. Berrang et al. does not contemplate an arrangement in which the bridge at least partially encapsulates the two housing sections, much less a bridge that encapsulates first and second housings of first and second modules, respectively.

The Office Action further stated that column 9, lines 58-62 of Berrang et al. teaches that "the housing sections 2 and 3 and bridge structure 6 are preferentially coated with gold, and, in a further embodiment, further coated with titanium, platinum, medical grade silicone, or any combination thereof."<sup>7</sup> The Office Action characterized these coatings as an overmold.

Applicant respectfully disagrees that the coatings referred to at column 9, lines 58-62 of Berrang et al. constitute an overmold, and submits that the Examiner has misinterpreted the scope and content of Berrang. The gold layer is not an overmold that at least partially encapsulates housings of respective modules, as suggested by the Office Action. Instead, the gold layer forms a single housing for elements 2 and 3, and elements 2 and 3 are two sections devoid of individual housings within the single housing provided by the common gold layer.<sup>8</sup> For example, FIG. 2 of Berrang et al. illustrates a gold foil 27 surrounding the entire Berrang device. Berrang et al. also teaches that the epoxy surfaces 28 and 31 are covered with the gold layer, which is designed to

<sup>5</sup> Col. 11, lines 60-63.

<sup>6</sup> Col. 3, lines 33-35.

<sup>7</sup> Office Action at page 6, item 1.

<sup>8</sup> See *id.* at column 9, lines 58-62 and column 3, lines 32-35.

Application Number 10/731,869  
Responsive to Office Action mailed March 8, 2007

bond directly to the outside edge of the ceramic substrates 24 and 25, thus creating a sealed, hermetic covering over the components mounted onto each of the ceramic substrates 24 and 25.

Applicant's claim 1 specifically requires first and second modules comprising correspond housings in addition to the overmold. As previously discussed, the elements 2 and 3 do not have separate housings. The elements 2 and 3 of Berrang et al. share a housing (i.e., the gold layer), and in no way have respective first and second housings, as required by Applicant's independent claim 1. Nothing in Berrang et al. teaches or suggests that elements 2 and 3 are enclosed in a housing other than the gold layer so as to be considered modules each comprising a respective housing. Furthermore, because the gold layer is the housing for elements 2 and 3, which the Office Action characterized as "modules," the gold layer cannot be an overmold that at least partially encapsulates each of the respective housings of the at least first and second modules, as required by claim 1.

For the reasons discussed above with respect to Applicant's independent claim 1, Berrang et al. fails to teach or suggest a implantable medical device comprising a first module that includes control electronics housed within a first housing, a second module that includes a power source that provides power to the first module housed within a second housing, an interconnect member that flexibly couples the first and second housings, where the interconnect member is flexible in a plurality of directions and allows the first and second modules to have a plurality of degrees of freedom of movement relative to each other, and a flexible overmold that at least partially encapsulates the first and second housings, as recited by Applicant's independent claim 23.

Similarly, Berrang et al. fails to teach or suggest each and every element of Applicant's independent claim 39. Claim 39 recites an implantable medical device that comprises a first module that includes control electronics housed within a first housing, a second module that includes a power source that provides power to the first module housed within a second housing, and a hermetic interconnect member that flexibly couples the first and second housings, wherein the interconnect member is flexible in a plurality of directions and allows the first and second modules to have a plurality of degrees of freedom of movement relative to each other. In addition to the first and second modules comprising respective housings and an overmold, Berrang et al. fails to teach or suggest a hermetic interconnect member. The Office Action fails

Application Number 10/731,869  
Responsive to Office Action mailed March 8, 2007

to provide an indication of what element in Berrang et al. corresponds to a hermetic interconnect member. Assuming for purposes of argument only that the Office Action characterizes the bridge as an interconnect member, which Applicant disagrees with, nothing in the Berrang et al. disclosure teaches or even suggests that the bridge is hermetic. Accordingly, Berrang et al. cannot teach or suggest each and every element of Applicant's independent claim 39.

Applicant's independent claim 42 is directed toward an implantable medical device that comprises a first module comprising control electronics and a therapy delivery circuit housed within a first housing, a second module comprising a power source within a second housing, an interconnect member that flexibly couples the first and second modules and includes a conductor for delivery power from the power source to the control electronics and the therapy delivery circuit, and a flexible overmold that at least partially encapsulates the first and second housings. As discussed above with respect to independent claim 1, Berrang et al. fails to teach or suggest at least first and second modules each comprising a respective housing, as well as an overmold that at least partially encapsulates the first and second housings. For at least these reasons, Applicant's independent claim 42 is patentable over Berrang et al.

Berrang et al. also fails to teach or suggest each and every element of Applicant's independent claim 56 as amended. Claim 56 has been amended to clarify that an implantable medical device comprises a first module comprising control electronics within a first housing, a second module comprising a recharge coil within a second housing, a third module comprising a rechargeable power source within a third housing, an overmold that at least partially encapsulates the first and third housings, and a flexible tether member that connects the overmold and the second housing. Berrang et al. does not teach or suggest such elements, much less an arrangement in which control electronics and a rechargeable power source are provided in separate housings that are at least partially encapsulated by an overmold, and a recharge coil is provided within another housing that is connected to the overmold. Furthermore, the Office Action fails to point out how Berrang et al. anticipates such an arrangement of the control electronics, rechargeable power source, and recharge coil.

Berrang et al. fails to disclose each and every limitation set forth in independent claims 1, 23, 39, 42, and 56, and the claims dependent therefrom. Claims 2-22 depend from claim 1, claims 24-31 and 33-38 depend from claim 23, claims 40 and 41 depend from claim 39, claims

Application Number 10/731,869  
Responsive to Office Action mailed March 8, 2007

43-55 depend from claim 42, and claim 57 depend from claim 56. For at least these reasons, the Office Actions has failed to establish a *prima facie* case of unpatentability of Applicant's claims 1-31 and 33-57 under 35 U.S.C. §§ 102(e) and 103(a). Withdrawal of the rejection of claims 1-31 and 33-57 is respectfully requested.

**Provisional Rejection for Obviousness-type Double Patenting**

In the Office Action, claims 1-31 and 33-57 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application No. 10/731,638 (U.S. Publication No. 2004/0176817), claims 1-14 of copending Application No. 10/730,878 (U.S. Publication No. 2004/0176816), claims 1-23 of copending Application No. 10/731,699 (U.S. Publication No. 2004/0172090), claims 1-54 of copending Application No. 10/730,873 (U.S. Publication No. 2004/0176814), claims 1-27 of copending Application No. 10/731,867 (U.S. Publication No. 2004/0176673), and claims 1-2 and 14-16 of copending Application No. 10/731,868 (U.S. Publication No. 2004/0173221).

Applicants note the provisional status of this rejection. Accordingly, Applicants will address this issue if and when the rejection is formally applied.

**New Claims**

Applicant has added claims 58-61 to the pending application. No new matter has been added by the new claims. Support for claims 58-61 can be found at, for example, paragraphs [0048] and [0049] of Applicant's originally filed disclosure. Berrang et al. fails to disclose or suggest the inventions defined by Applicant's new claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed inventions.

For example, Berrang fails to disclose or suggest an implantable medical device including a first module comprising at least two modules comprising separate housings, where at least one of the housings comprises a hermetic housing, as recited by new claims 58-61. As previously discussed, Berrang et al. fails to teach or suggest first and second modules comprising respective housings. The Office Action reasoned that housing sections 2 and 3 were modules. However, sections 2 and 3 do not have separate housings, and Berrang et al. specifically states that the

Application Number 10/731,869  
Responsive to Office Action mailed March 8, 2007

RECEIVED  
CENTRAL FAX CENTER

epoxy that is used to coat and encapsulate the internal components of elements 2 and 3 do "not provide a true hermetic or hermetic like seal."<sup>9</sup> For this reason, Berrang et al. provides a single gold coating over the encapsulant surface.<sup>10</sup> Thus, Berrang et al. does not teach or suggest a device including at least two modules comprising separate housings, where at least one of the housings comprises a hermetic housing, as recited by Applicant's new claims 58-61.

JUN 08 2007

### CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date:

June 8, 2007

SHUMAKER & SIEFFERT, P.A.  
1625 Radio Drive, Suite 300  
Woodbury, Minnesota 55125  
Telephone: 651.735.1100  
Facsimile: 651.735.1102

By:

Jessica H. Kwak  
Name: Jessica H. Kwak  
Reg. No.: 58,975

<sup>9</sup> Berrang at column 3, lines 59-65.  
<sup>10</sup> *Id.*